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32954	7590	06/20/2006	EXAMINER	
JAMES C. LYDON 100 DAINGERFIELD ROAD SUITE 100 ALEXANDRIA, VA 22314			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/913,643

Applicant(s)

JOKINEN ET AL.

Examiner

Blessing M. Fubara

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16,18,19 and 24-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,18,19 and 24-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges request for reconsideration filed 03/01/06 and 03/27/06. No claims are currently amended. Claims 16, 18, 19 and 24-34, are pending.

The action is made non-final to address 35 USC 112 issues.

#### **The claims:**

Claims 28 and 29 are claims directed to method of administering biologically active agent to a human or animal; the method comprises implanting or injecting or mucosally attaching the delivery device of claim 30 where the fiber comprises active agent.

Claims 34, 16, 18 and 19 are directed to method for preparing biodegradable silica fiber, the method comprises correlating a desired biodegradability of a silica fiber with a viscosity of a silica sol, preparing the silica sol and spinning the fiber from said sol; and the spinning process begins when the viscosity of the silica sol reaches a value correlating to said desired biodegradability of the silica fiber (claim 34). Claims 16, 18 and 19 depend from claim 34 and further define the method.

Claims 30-33 and 24-27 are directed to controllably biodegradable silica fiber that has a solubility of 0.2 to 20 wt%/hr and the fiber is spun from silica sol, biodegradation rate of the fiber is adjusted by controlling the viscosity of the starting point of the spinning (claim 30) or adjusting the biodegradation rate of the fiber by controlling the viscosity of the spinning sol (claim 32).

The composition claims are product by process claims and “ product-by-process claims are not limited to the manipulations of the recited steps, only the structure

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implied by the steps.” And “[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). (MPEP 2113 [R-1].

Applicants neither commented or traversed the interpretation of the claims presented above.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 34, 16, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the

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claimed invention. There is no description in the specification correlating desired biodegradability of silica fiber with the viscosity of the silica sol before spinning the fiber.

Claims employing the mental process of correlating desired biodegradability of a silica fiber with a viscosity of a silica sol without a defining when to start the spinning is not described and the specification does not inform the public of the limits of the monopoly asserted. The expression “correlating a” represents only an invitation to experiment regarding when the spinning of the fiber would begin from the silica sol.

#### ***Response to Arguments***

4. Applicants' arguments filed 3/1/06 and 3/27/06 have been fully considered but they are not persuasive in view of the following reasons below:

Applicants argue that “the specification explicitly states that fiber biodegradability can be adjusted for desired purposes by controlling the viscosity of the spinning solution for determining the starting point of the spinning (page 5, lines 6-10). The silica sol is spinnable within a certain time period, rather than at a single point, and the silica sol viscosity increases during this time period. In the earlier stage of spinnability the silica polymers are somewhat smaller and they are packed easier, forming denser structures than the larger silica polymers of the later stage of spinnability. Fibers spun in the earlier stage of the spinnability period degrade more slowly in simulated body fluid than fibers spun in the later stage of spinnability (Specification page 5, lines 11-24 and page 16, lines 17-21). Example 3 illustrates silica fiber biodegradability as a function of the starting point of the spinning process, as quantitatively measured by silica solubility in SBF/wt-%/h.” However, it is noted that there is no categorical statement in the specification directing the artisan to practice the invention at a specified

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viscosity, be it a range or clear single point and because of that silence, the artisan is invited to try the correlation by unduly experimenting with the data in Figures 8, 10 and 12 to arrive at when the spinning of an aged sol would start in order to produce applicants' silica fiber.

Applicants' admission of lack of any one single point at which to begin the spinning supports the need for a clear guidance in the description as to when to begin the spinning of the silica sol.

Regarding Example 3, it is noted that Example 3 is what the Example is, spinning viscosity as a function of the starting point of the process in Figure 5 and not a clear guidance that the spinning of the sol begins or ought to begin at a specified range of viscosities or specific viscosity.

Regarding the Drawing, it is also noted that the Drawings do not direct the artisan to use the process to produce applicants' product, there is no definite guidance as to when the spinning should begin.

Regarding the ordinary skilled artisan, it is noted that the person of ordinary skill in the art would be guided by what applicants describe in the second full paragraph of page 5 of the response filed 3/1/06 and 3/27/06 to experiment with a start time for the spinning process because of lack of clear written guidance on how to make applicants' product, and this invitation to experiment does not meet the written description requirement.

5. Claims 24-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. There is no description in the specification for “controllably biodegradable silica fiber.”

Claims employing “controllably biodegradable silica fiber” are not described and the specification does not inform the public of the limits of the monopoly asserted. “Controllably biodegradable silica fiber” has not been defined in the as filed specification.

6. The rejection of claims 34, 16, 18 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because applicants appear to agree with examiner that correlating biodegradability with viscosity is examined as correlating dissolution with starting viscosity of the sol.

7. Claims 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because “controllably biodegradable silica fiber” is not clear and the claims do provide a definition for what that means.

#### ***Claim Rejections - 35 USC § 102***

8. The rejection of claim 34 under 35 U.S.C. 102(b) as being anticipated by Ahola et al. (WO 97/45367) is withdrawn because applicants’ argument that Ahola does not specifically

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disclose the mental process of correlating has been considered. However, although, such a mental process is/may be inherent and arbitrary, the rejection under 35 USC 102 is withdrawn for lack of explicit disclosure. However, this rejection may be reintroduced if further evidence of inherent thought process in correlating fiber dissolution with start time of spinning supports lack of novelty of the claimed invention.

9. The rejection of claims 34, 16, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US 4,919,871) is withdrawn because Lin does not specifically state a process of correlating desired biodegradability of a silica fiber with a viscosity of a silica gel. However, this rejection may be reintroduced if further evidence of inherent thought process in correlating fiber dissolution with start time of spinning supports lack of novelty of the claimed invention.

10. The rejection of claims 34, 16, 18 and 19 and 24-33 under 35 U.S.C. 102(e) as being anticipated by Peltola et al. (US 6,632,412) is withdrawn because applicants statement that Peltola is not prior art in view of the effective date of the Peltola reference is persuasive.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 16, 18, 19 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. (WO 97/45367).



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Ahola discloses preparation of biodegradable silica-xerogel fibers by drawing the fibers from silica sol prepared by sol-gel process; the start of the drawing process was found to be approximately 10 mPas (Example 2).

Claim 34 is generic to preparation of silica fiber. Ahola clearly discloses preparing silica sol, spinning the fiber from the silica sol and the spinning begins at a determined viscosity of the sol. The silica fiber of Ahola is biodegradable and dissolved in simulated body fluid. Since Ahola starts the spinning process at a specified viscosity, a determination was made to spin the sol at a specific viscosity.

Ahola starts drawing the fibers from the sol at a specified viscosity of 10 mPas. Ahola does not specifically state the viscosity is correlated with biodegradability of the fiber and it is from such a correlation that the start viscosity for the spinning process is determined at 10 mPas. However, since the fiber of Ahola is controllably dissolvable, it stands to reason that a certain start viscosity is necessary before the sol can be spun. Furthermore, starting the spinning at a desired biodegradability of the silica fiber in relation with the viscosity of the silica sol is an arbitrary process and Ahola would have mentally made the correlation by starting the spinning of the fiber at a desired viscosity of 10 mPas. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to spin the silica sol according to Ahola. One having ordinary skill in the art would have been motivated to spin the sol at a start viscosity to produce dissolvable fiber.

Regarding claims 16, 18 and 19, which are directed to the viscosity at which the spinning begins, it is noted that the disclosed start viscosity of 10 mPas is significantly less than the start viscosity of 10,000 to 100,000 mPas. While the claimed and disclosed viscosities are different,

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there is no further data showing the reasons for the difference, for example, the claims have not recited concentration of the silica sol that would yield a viscosity of the type recited. The prior art does not indicate the concentration of the sol that would give disclosed viscosity. There is also no demonstration that the claimed viscosity provides unexpected results to the spun fiber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to start the spinning at 10 mPas as the viscosity predetermined for the spinning. One having ordinary skill in the art would have been motivated to spin the sol at a viscosity that would be expected to yield a fiber having the desired dissolution.

***Response to Arguments***

13. Applicants' arguments filed 3/1/06 and 3/27/06 have been fully considered but they are not persuasive.

Regarding Ahola's failure to disclose the correlation step of claim 34, it is noted that the correlation is an arbitrary determination of when the spinning of the fiber would begin. Examiner takes the position that the clear fact that Ahola spins the fiber at a viscosity of 10 mPas is an indication that Ahola thoughtfully considered spinning the fiber and this exercise rises to a level of the arbitrary and mental process of consideration of the instant claims clearly showing that Ahola considered some arbitrary parameter in starting the spinning at the specified viscosity. It is further noted that no specific start viscosity is claimed.

14. Claims 24-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahola et al. (WO 97/45367).

Ahola is discussed above. In Example 2, the spinning started at viscosity 10 mPas, the fibers were dissolved (page 14, lines 6-8) in simulated body fluid (23 °C and pH of 7.54; 37 °C

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and pH of 7.40); this section does not disclose the dissolution rate. In lines 18-20 at page 14, Ahola discloses that the fibers kept at room temperature dissolved “at significant amounts,” and that 10-weight% of the room temperature fibers stored in a desiccator dissolved within 4 weeks. Furthermore, in vivo dissolution test conducted on rats by implanting silica fibers showed that the fibers have been integrated into the surrounding connective tissues after two weeks of the implantation (page 14, line 27 to page 15 line 18). Ahola also discloses that the fibers can be used as delivery devices that can be implanted or injected or attached to mucosa of human or animal body to deliver any of the drugs listed on page 6, lines 11-37 (page 4, line 32 to page 6 line 37). The disclosure of the fiber containing drugs read on claims 24-27 and the disclosure that the fiber containing the bioactive agent(s) can be implanted or injected or attached to the mucosa of human or animal reads on claims 28 and 29.

However, Ahola does not disclose the claimed dissolution rate of 0.2 to 20 wt%/h. A complete or near complete dissolution of implanted fiber was observed 2 weeks after implantation. A desiccated fiber dissolved at a rate of 10 wt%/4 weeks. Ahola fails to disclose the mg-amount of the fiber upon which the dissolution was conducted. There is also no demonstration in applicants’ specification that the rate of dissolution provides unusual results to the delivery device of the claims. Both the claimed fiber and the fiber of the prior art dissolve and deliver bioactive agents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the fiber of Ahola. One having ordinary skill in the art has the technical know how to determine the rate of dissolution of the fiber implanted in the rat. In the absence of factual evidence, the claimed dissolution rate is not patentable over the prior art fiber that dissolves after 2 weeks of implantation.

***Response to Arguments***

15. Applicants' arguments filed 3/1/06 and 3/27/06 have been fully considered but they are not persuasive.

Response to Ahola's failure of correlating biodegradability with viscosity has been made above. The same response as provided above is given for applicants' argument that Ahola does not correlate desired biodegradability of the silica fiber and the specific viscosity; and is also noted that a desired biodegradability is relative and arbitrary and Ahola made the consideration for "desired biodegradability" by starting the spinning at a specified viscosity. Regarding the issue of motivation, it is noted that, the motivation is to produce a controllably dissolvable silica. Regarding the solubility rate of 0.2 to 20 wt%/h vs. 10 wt%/4 weeks, it is also noted that a complete or near complete dissolution in 2 weeks after implantation. Both the claimed fiber and the fiber of the prior art dissolve and deliver bioactive agents.

16. Claims 34, 16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (US 4,919,871).

Lin discloses method of preparing silica fibers by preparing a sol, ageing the sol until a desired spinning viscosity is reached and the sol is then drawn into fibers (Example 1; column 2, lines 19-56). The sol is aged to a room temperature viscosity of 129 poise (12900 mPas) in Example XII and this viscosity meets the viscosity limitations of claims 16, 18 and 19. The disclosure that the sol is aged to a desired spinning viscosity reads on determination of spinning viscosity that would produce the desired fiber.

As discussed above, Lin's method of preparing fibers comprises ageing the sol to a desired spinning viscosity. While Lin does not specifically describe correlating start viscosity

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with biodegradability, Lin clearly discloses ageing the sol to a desired spinning viscosity at which viscosity the spinning process may begin. Therefore, one having ordinary skill in the art would have been motivated to determine a viscosity at which spinning would start to produce the desired fiber.

***Response to Arguments***

17. Applicants' arguments filed 3/1/06 and 3/27/06 have been fully considered but they are not persuasive.

Regarding Lin's failure to specifically disclose correlation of biodegradability to the viscosity of the silica sol, it is noted that the desired biodegradability is relative and arbitrary and Lin made the consideration for "desired biodegradability" by starting the spinning at a specified viscosity.

While applicants insist that the biodegradability of the fiber is conducted in simulated body fluid, it is noted that the claims do not specify the viscosity at which to start the spinning. Regarding the drying step, it is noted that the claims do not exclude drying step and does not exclude drying in ammonia. There is no factual evidence that the fiber of Lin does not biodegrade and in the absence of factual showing, the claimed invention is obvious over Lin. The claimed invention does not exclude ammonia treatment. Regarding the starting the viscosity, it is noted that Lin employs consideration of when to start the spinning process and as such starts the spinning process at 12900 mPas; in regards to modifying the start-spin-viscosity, it is noted that the requirement for the start-spin viscosity is arbitrary in claim 34.

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18. Claims 16, 18, 19 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 196 09 51, English translation provided by applicants. The DE reference discloses viscosity of 0.05-50 Pas (50-50,000 mPas) and a preferred viscosity of 0.5 to 2 Pa (500 to 2,000 mPas) (page 7, last 2 lines of the last paragraph). This viscosity range lies within the claimed viscosity range 1,000 to 100,000 mPas and thus meets the limitations of claims 16, 18 and 19. Claim 34 does not recite the starting viscosity. The DE reference discloses that the degradation rate of the fibers can be adjusted to the requirements of each purpose of use and that the fibers degrade under condition prevailing in the human organism and specifically dissolve in body-like fluids (second full paragraph of page 3; 4<sup>th</sup> full paragraph of page 4) and this meets the limitation of simulated body fluid. The DE reference further discloses that the fiber dissolves/degrades at 10-100 nm fiber radius per day and a fiber having a radius of 10  $\mu\text{m}$  completely dissolves in 50-500 days (4<sup>th</sup> full paragraph of page 4).

Regarding correlation of biodegradability with viscosity, it is noted that, to the extent that biodegradability is synonymous with dissolution, the correlation of dissolution with viscosity reads on starting the spinning process at a predetermined sol viscosity to produce the desired fiber having desired dissolution.

The prior art discusses dissolution in terms of radius of the fiber/day. The claimed invention discusses dissolution in terms of wt%/hr. The radius of fiber/day dissolved can be converted to radius of fiber/hr by the person of ordinary skill or the skilled artisan. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was to prepare silica fiber according to the DE reference. One having ordinary skill in the art would be motivated to prepare the fiber of the DE reference with the expectation that a fiber having a

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radius of 10 mm would dissolve/degrade within 50-500 days. One having ordinary skill in the art would have the technical know how to determine the degradation/dissolution rate in wt%/day or wt%/h and to adjust the degradation rate according to the desired use as suggested by the DE reference. In the absence of factual evidence the claimed dissolution rate does not patentably distinguish the fiber of the prior art having dissolution rate in radius/day, which can be converted to radius/h.

***Response to Arguments***

19. Applicants' arguments filed 3/1/06 and 3/27/06 have been fully considered but they are not persuasive.

Regarding the DE '551 failure to disclose, teach or suggest the correlation step of the claimed method, it is noted that a consideration went into the decision to start the spinning process at the desired viscosity, which in the case of the DE '551 is from 50-50,000 mPas. The claimed invention in claim 34 sets forth an arbitrary process of correlating biodegradability with viscosity of the sol without a specific requirement to spin the fiber at a specified viscosity or viscosity range, and the process of the DE '551 considered the spinning to start at a desired specific viscosity, which is indicative of a consideration of when to start the spinning.

Regarding the dissolution of times of 21 days vs. 50 days, it is noted that there is no factual showing of the unexpected result of the fiber dissolving in 21 days over 50 days because fibers of the prior art dissolves as does the claimed fiber; furthermore, the dissolution in DE '551 is determined in terms mm of fiber that dissolves per day and the claimed invention uses different criteria in the determination of the dissolution parameter.

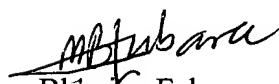
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20. The rejection of claims 34, 16, 18 and 19 35 U.S.C. 103(a) as obvious over Peltola et al. (US 6,632,412) is withdrawn in view of applicants' persuasive argument that the Peltola is not available as art because the effective date of the Peltola is after the priority date of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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